

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

<p>IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION</p>	
<p>THIS DOCUMENT RELATES TO:</p> <p><i>The City of New York v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 04-CV-06054</p> <p><i>County of Albany v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0425</p> <p><i>County of Allegany v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0236</p> <p><i>County of Broome v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0456</p> <p><i>County of Cattaraugus v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0256</p> <p><i>County of Cayuga v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0423</p> <p><i>County of Chautauqua v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0214</p> <p><i>County of Chemung v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-6744</p> <p><i>County of Chenango v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0354</p> <p><i>County of Columbia v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0867</p> <p><i>County of Cortland v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0881</p> <p><i>County of Dutchess v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 05-CV-6458</p> <p><i>County of Essex v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0878</p> <p><i>County of Fulton v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0519</p>	<p>MDL NO. 1456 Civil Action No. 01-12257-PBS</p> <p>Judge Patti B. Saris</p> <p>PLAINTIFFS' JOINT SURREPLY IN FURTHER OPPOSITION TO DEFENDANT MEDIMMUNE, INC.'S INDIVIDUAL MOTION TO DISMISS</p>

County of Genesee v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-00267

County of Greene v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0474

County of Herkimer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00415

County of Jefferson v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0715

County of Lewis v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0839

County of Madison v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00714

County of Monroe v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6148

County of Nassau v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 04-CV-05126

County of Niagara v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06296

County of Oneida v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0489

County of Onondaga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0088

County of Ontario v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6373

County of Orleans v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6371

County of Putnam v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 05-CV-04740

County of Rensselaer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00422

County of Rockland v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-7055

County of Schuyler v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6387

County of Seneca v. Abbott Laboratories, Inc., et al.

W.D.N.Y. Case No. 05-CV-6370

County of St. Lawrence v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0479

County of Saratoga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0478

County of Steuben v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6223

County of Suffolk v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 03-CV-12257

County of Tompkins v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0397

County of Ulster v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 06-CV-0123

County of Warren v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0468

County of Washington v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0408

County of Wayne v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06138

County of Westchester v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-6178

County of Wyoming v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6379

County of Yates v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06172

MedImmune's reply memorandum ("MedImmune Reply"),¹ makes two critical admissions that soundly establish plaintiffs' fraud claims based on false WACs and AWP, thus defeating its motion to dismiss: 1) drugs described as "physician administered" like Synagis can and are reimbursed based on AWP, and 2) that, as alleged in the CC, administration costs are factored into the AWP spread of Synagis. *See* MedImmune Reply at 2-3, fn 6. By doing so, MedImmune bolsters both the irrelevance of the "physician administered" label to plaintiffs' claims and the fraudulent nature of its AWP.

MedImmune maintains that plaintiffs' allegations related to its "physician administered" drugs do not establish a reasonable inference of fraud because (i) plaintiffs did not allege that MedImmune represented AWP and WAC to reflect actual cost nor did plaintiffs define AWP or WAC; (ii) MedImmune's drugs were reimbursed at "actual cost" pursuant to New York Statute; and (iii) plaintiffs only allege spread for one of the three drugs named in their complaints.

MedImmune's argument is misguided and incorrect. The fact that a physician is reimbursed at "actual cost" is irrelevant to plaintiffs' claims concerning reimbursement for MedImmune drugs based on AWP. MedImmune admits its drugs were reimbursed on the basis of AWP, as plaintiffs allege, and MedImmune admits that its AWP do not merely reflect an average of wholesale prices but include an extra amount to cover "administration services", as plaintiffs also allege. In addition, MedImmune is incorrect to suggest that plaintiffs are required to plead a specific spread for every MedImmune drug at issue. *See* MedImmune Opp. at 2. Moreover, MedImmune's admission that its AWP are inflated to cover "administration services" (in addition to making no sense given that those who actually administer its drugs are typically not reimbursed based on AWP) by itself confirms that MedImmune's AWP do not reflect true

¹For clarity and consistency, plaintiffs use the same definitions of all terms and cases cited in their corresponding individual opposition memorandum ("MedImmune Opp."). Additionally, all other causes not addressed herein are addressed in Plaintiffs Consolidated Sur-Reply to Defendants Motion to Dismiss, filed contemporaneously herewith (referred to herein as "Consolidated Sur-Reply).

wholesale prices and that plaintiffs' allegations of fraudulent inflation are made in entirely good faith. The following summarizes why MedImmune's motion should be denied in its entirety:

First, MedImmune admits -- as it must -- that "physician administered" drugs like Synagis are reimbursed at AWP as well as at "actual cost" under New York Medicaid.² See MedImmune Reply at 2. Synagis is distributed by "Assignment of Benefit Distributors, who are reimbursed at AWP minus a percentage." MedImmune Reply at 3.

Second, plaintiffs' claims concern reimbursements made to health care providers, including specialty pharmacies, based on the drug NDC and corresponding AWP.³ See CC at ¶¶ 5, 83-85; NSAC at ¶¶ 69-73. See also N.Y. Soc.Serv. L. §367-a(9)(ii).

Third, Synagis, like all MedImmune drugs, has been reimbursed by New York Medicaid to providers at AWP.⁴

Fourth, MedImmune contends it never represented that AWP or WAC means actual cost.

²The phrase "physician administered" has no operative or controlling significance in terms of reimbursement under New York Medicaid or whether such reimbursement is based on AWP. The Statute provides that New York Medicaid reimburses "for drugs provided by medical practitioners and claimed separately by the practitioners, [at] the actual cost of the drugs to the practitioners." N.Y. Soc. Serv. Law §367-a(9) (emphasis added). Thus, in order for a physician administered (or any other) drug to be reimbursed at "actual cost", the "medical practitioner" must: (i) provide the drug; and, (ii) claim reimbursement separately. See *id.* Plaintiffs concede that the plain meaning of the statute says that drugs so provided and claimed are reimbursed based on actual cost.

³MedImmune implies that plaintiffs seek to equate the reimbursement of physicians at "actual cost" under New York Medicaid with either WAC or AWP. They are not.

⁴In January 1999, the NY Department of Health ("NY DOH") issued a Medicaid Update entitled "Medicaid Coverage Of SYNAGIS (PALIVIZUMAB)" addressing the reimbursement of Synagis:

"Medicaid reimburses for **SYNAGIS** when billed by Medicaid-enrolled physician and pharmacy providers. It can be administered in the home by Medicaid-enrolled Home Health Care provider professional staff. Similarly, it can be administered by pediatric long term care facility licensed caregivers. Physician providers may bill on a paper claim under code **90749** (unlisted immunization procedure), attaching a copy of the invoice to the claim. [...] Pharmacy providers should enter the SYNAGIS NDC number into the on-line billing system as they would for any prescription pharmaceutical" (bold in original, emphasis added)."

See http://www.health.state.ny.us/health_care/medicaid/program/update/1999/0199med.htm#coverage. Of note is that physician providers submit a J-Code (in bold above) for reimbursement, while the providers submit an NDC for reimbursement. Certainly MedImmune knew this.

Also, in May 2001, the NY DOH issued a Medicaid Update entitled "Attention Pharmacy Providers Serving Nursing Home & Child Care Agencies" informing Pharmacy Providers to Nursing Homes and Child Care Facilities of drugs for which they may seek reimbursement, including Synagis, Respigam and Cytogam and many other "physician administered" drugs. See http://www.health.state.ny.us/health_care/medicaid/program/update/2001/may2001.htm#att

Reply at 1. But actual costs are not the issue here; accurate AWP's are. MedImmune is legally obligated to report true wholesale pricing information to the government in order to have its products paid for from the public fisc.⁵ See *North Memorial Medical Center v. Gomez*, 59 F.3d 735, 739 (8th Cir. 1995) (citing *Heckler v. Community Health Servs.*, 467 U.S. 51, 64-65 (1984)). Plaintiffs allege that it does not do so.

Fifth, MedImmune admits that the AWP for Synagis is used "to cover the extraordinary costs encountered in administering Synagis". MedImmune Reply at fn 6. In addition to conceding a false inflation of AWP, the argument makes no practical sense. Physicians or practitioners seeking reimbursement for administering Synagis do so based on J-Codes, which includes compensation for the administering service. Those reimbursed for Synagis based on AWP's are not "practitioners" or others incurring administering service costs. Why should MedImmune be charging Medicaid for a service that is not provided? Moreover, even if an administering service were provided by those reimbursed based on AWP, the plain meaning of AWP is "average wholesale price" not "average wholesale price + administering service cost". This admission by MedImmune, even without a spread, establishes a strong inference of fraud that MedImmune's AWP's are false.

Sixth, plaintiffs' response to MedImmune contention that plaintiffs' allegations lack specificity for Best Price claims is set forth at Point IV of their Consolidated Sur-Reply, which is incorporated herein.

Seventh, MedImmune does not dispute -- nor can it -- that prior to June 9, 1994 New York Medicaid reimbursed all MedImmune drugs to all claimants based on AWP, irrespective of any "physician administered" description. See MedImmune Reply at 3.

⁵MedImmune also claims that plaintiffs "have not alleged, if ever, they paid for MedImmune drugs based on allegedly inflated AWPS or WACs." *Id.* at 3. To the contrary, that is exactly what they have done., See CC at ¶¶589-590; NSAC at ¶¶ 489-496.

CONCLUSION

For the reasons set forth herein and in Plaintiffs' Opposition Memorandum, MedImmune's individual Motion to Dismiss should be denied in its entirety.

Dated: June 2, 2006

Respectfully submitted,

**City of New York and all captioned Counties
except Nassau, by**

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